

## REMARKS

Applicant respectfully requests consideration. Claims 10, 14-19, 25 and 26 were previously pending in the application. By this amendment Applicant is canceling claims 17 and 26. Claims 10, 14, 15, 18, 19 and 25 have been amended. Support for the claim amendments can be found throughout the specification and in the claims as filed. As a result claims 10, 14-16, 18, 19 and 25 are pending for examination with claims 10, 18 and 19 being independent claims. No new matter has been added.

### Information Disclosure Statement

The Examiner has indicated that the Hegenbart reference cited in the IDS of April 20, 2006 cannot be considered, as a copy was not available. Applicant is providing a new IDS and PTO Form 1449 that cites five Hegenhart publications, copies of which are also provided.

### Rejections under 35 U.S.C. §112

The Examiner rejected claim 26 for allegedly failing to comply with the written description requirement. Without conceding the correctness of the Examiner's rejection, Applicant has canceled claim 26, and, therefore, believes the rejection is now moot.

The Examiner rejected claims 10, 14-17, 19 and 26 for allegedly failing to comply with the enablement requirement.

Applicant has made claim amendments without conceding the correctness of this rejection. Applicant has also canceled claims 17 and 26 without conceding the correctness of the rejection. Applicant maintains that the claims as amended are sufficiently enabled based on the teachings provided in the specification as well as the high level of knowledge in the art. The claims as amended are now directed to methods for producing or obtaining decorin in the milk of a non-human mammal as well as to transgenic non-human mammals that produce decorin in their milk.

The written specification provides detailed working examples of how to express human decorin in the mammary glands of mice (page 50-52) and goats (page 55-58). The specification

further teaches how to harvest and purify milk from mammary glands. In addition, page 50 of the written description provides a working example of a transgene that directs the expression of decorin in the mammary gland. Examples of other transgenes that may be used to direct expression in the mammary gland are also provided on at least page 3, lines 8-12. Applicant maintains that a person of ordinary skill in the art could apply the teachings of the instant specification and combine them with the teachings routine in the art at the time of filing and arrive at the methods and non-human mammals of the claims.

Accordingly, withdrawal of the rejection under 35 U.S.C. §112 is respectfully requested.

Rejection under 35 U.S.C. §102

The Examiner rejected claim 19 under 35 U.S.C. §102(b) as allegedly being anticipated by Hering et al. (1996, Analytical Biochemistry 240: 98-108). According to the Examiner, Hering et al. teach a transgenic non-human organism that expresses transgenic decorin.

Without conceding the correctness of the Examiner's rejection, Applicant has amended claim 19 such that it is directed to a transgenic non-human mammal that expresses transgenic decorin. As the Examiner has indicated that Hering et al. teach the production of decorin in bacterial cells, Applicant believes that this rejection is now moot.

Accordingly, withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

Rejection under 35 U.S.C. §103

The Examiner rejected claims 10, 14-19 and 25 under 35 U.S.C. §103 as allegedly being unpatentable over Houdebine et al. (US Patent 5,965,788) in view of Isaka et al. (1996, Nature Med 2: 418-423) and Roberts et al. (1992, Gene 121: 255-262). The Examiner argues that one of ordinary skill in the art would have been motivated to substitute the promoter and the nucleic acid sequence encoding decorin in order to obtain a transgenic mammal that expresses decorin, because Houbedine allegedly teaches that expressing recombinant protein in milk resulted in large amounts of expressed protein, because Isaka allegedly teaches that recombinant decorin is difficult to make but has therapeutic effects and because Roberts allegedly teaches that beta-casein is the most

abundantly produced protein in milk. The Examiner also argues that there is a reasonable expectation of success given the Houbedine results and Roberts' teaching that goat beta-casein promoter expressed proteins at high levels.

Applicant respectfully traverses. Applicant maintains that the Examiner, in the arguments presented, has not sufficiently demonstrated that the successful production of decorin in the milk of a non-human mammal as claimed would have been reasonably expected at the time of filing of the instant application. It is noted that the only teachings offered by the Examiner in regard to the ability to express decorin are the teachings of Isaka which demonstrate that its expression was difficult. The Examiner has not demonstrated why at the time of filing decorin would have been expected to be expressed at high levels in light of the teachings of Isaka if *arguendo* the teachings of the references could be combined to obtain the methods and non-human mammal of the rejected claims as asserted by the Examiner. Applicant maintains that the Examiner has improperly used hindsight to arrive at the conclusion of a reasonable expectation of success with the references cited.

Accordingly, withdrawal of the rejection under 35 U.S.C. §103 is respectfully requested.

**CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Dated: December 21, 2006

Respectfully submitted,  
*Meade et al., Applicant*

By 

Janice A. Vatland, Ph.D.

Registration No.: 52,318

WOLF, GREENFIELD & SACKS, P.C.

Federal Reserve Plaza

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

(617) 646-8000